Effectiveness of Neuromuscular Taping on Balance, Proprioception, Pain and Nerve Conduction parameters in patients with Diabetic Peripheral Neuropathy

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SYNOPSIS SUBMITTED

To

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Mullana, Haryana, India

In partial fulfillment of the requirements for the degree

Doctor of Philosophy

(Physiotherapy)

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Declaration

I hereby declare that this dissertation entitled, **"Effectiveness of Neuromuscular Taping on Balance, Proprioception, Pain and Nerve Conduction parameters in patients with Diabetic Peripheral Neuropathy"** is an outcome of the original research work undertaken and carried out by me, under the supervision of **Prof. (Dr.) Manu Goyal ,** Maharishi Markandeshwar Institute of Physiotherapy and Rehabilitation, Maharishi Markandeshwar (Deemed to be University), Mullana-Ambala, Haryana. This is an original work submitted only to Maharishi Markandeshwar (Deemed to Be University), Mullana-Ambala, Haryana, and is free of any plagiarism at the time of submission.

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This is to certify that the PhD thesis synopsis/protocol on **"Effectiveness of Neuromuscular Taping on Balance, Proprioception, Pain and Nerve Conduction parameters in patients with Diabetic Peripheral Neuropathy"** has been done by KANIKA, Roll No. 1828752, under my supervision. I am satisfied with the work presented by the candidate towards the partial fulfillment of Doctor of Philosophy (Ph.D.) in Physiotherapy. This is an original work submitted only to Maharishi Markandeshwar (Deemed to be University), Mullana-Ambala, Haryana, and is free of any plagiarism at the time of her submission.

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LIST OF ABBREVIATIONS

DM	Diabetes Mellitus
DPN	Diabetic Peripheral Neuropathy
SSRIs	Selective Serotonin Reuptake Inhibitors
NMT	Neuromuscular Taping
BBS	Berg Balance Scale
LANSS	Leeds Assessment for Neuropathic Symptoms Score
MNSI	Michigan Neuropathy Screening Instrument
EG	Experimental Group
CG	Control Group
TENS	Transcutaneous Electrical Nerve Stimulation
NCV	Nerve Conduction Velocity

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Abstract

Background: Neuromuscular taping (NMT) has found be effective in improving motor, sensory and balance impairments in many neuromuscular and musculoskeletal conditions but no research has been done till date to evaluate the effect of neuromuscular taping on balance, proprioception, pain and nerve conduction in patients with diabetic peripheral neuropathy (DPN).

Purpose: To estimate the effectiveness of NMT on balance, proprioception, pain and nerve conduction parameters in patients with DPN.

Methodology: A randomized controlled trial will be done on 50 patients with DPN aged 40-60 years, scored ≥ 2/13 on physical appearance and ≥1/10 on physical examination of Michigan neuropathy screening instrument (MNSI), score >12 on LANSS score and <45 on BBS. Experimental group (EG) (n=25) will receive NMT at tibialis anterior, tibialis posterior and peroneus longus muscle and transverse arch of foot and TENS at tibial and peroneal nerve (80Hz, 50 Amp, 0.2 ms square pulses, 2 to 3 times sensory threshold) and control group (CG) will receive sham taping at ankle joint and TENS with same parameters as EG.

Data Analysis: Normality of data will be assessed through Kolmogorov Smirnov test. Demographics will be expressed using descriptive statistics. Repeated measure ANOVA/Friedman test, Wilcoxon signed rank test and independent t test/ Mann-Whitney U test will be chosen to find differences within group, differences between group and to compare the changes in mean values of the outcome measures at baseline, at 4 week and 8 week of intervention respectively.

Discussion: The results obtained upon completion of this study may provide a cost-effective non-invasive treatment option to improve the outcomes that will be measured in the present study in patients with DPN.

Mesh Words: Diabetic Peripheral Neuropathy, Taping, Transcutaneous Electrical

Nerve Stimulation, Balance, Proprioception, Pain, Nerve conduction Velocity.

1. INTRODUCTION

1.1 Diabetes

Diabetes, a common metabolic disease and a worldwide threat having the sky-high incidence with over 382 million diabetic patients in year 2013 and is still increasing day by day and expected to reach up to 592 million by 2035. Various complications are associated with long-term diabetes such as retinopathy, nephropathy, peripheral neuropathy, arteriosclerosis etc., among all peripheral neuropathy remains at top and have been found in 20-50% of all diabetic population.[1]

Developing countries with large population have huge number of diabetic patients in which India lies at the second number with 65.1 million diabetic patients. Seeing this rapid increase in number of diabetic population and changes in everyday lifestyle the burden of this disease is likely to increase day by day in coming years, thereby increasing the complications associated with it.[2] India has already been designated as “diabetes capital of world” and according to International Diabetes Federation by 2053 India would be expecting 69.9 million of diabetic population.[3] Genetic, obesity, urbanisation, lifestyle changes and environmental changes, all are the possible cause for diabetes.[4] Out of all these factors obesity is an utmost risk factor and It has been determined that India has a higher prevalence of diabetes in overweight and obese individuals compared to western countries. Lean individuals of India have also been found to have risk of being exposed to diabetics as those who are obese.[5]

In India, prevalence of diabetes is four times in rural area compared to urban areas and other sub-continental countries like Bhutan, Nepal. Bangladesh and Sri Lanka.[6] Low levels of high-density lipoproteins and dyslipidaemia in Indians making them more prone to develop coronary artery disease which in turn results in evolution of complications associated to diabetes in diabetic population at very early age of life (20-40years) compared to Caucasians, thereby indicating the extensive need of early screening and monitoring of diabetes population or prediabetics regardless of their age.[4]

1.2 Diabetic Peripheral Neuropathy (DPN)

1.2.1 Epidemiology

DPN is defined as “the presence of symptoms or signs of peripheral nerve dysfunction in people with diabetes after exclusion of other causes.[1,7] 60-70% of diabetic population experience mild to severe damage to nervous system which leads to DPN[8] which usually involves distal body parts and is characterised as distal symmetrical sensorimotor neuropathy which is progressive in nature and follows a "glove and stocking pattern".[9] DPN is found to be more associatedwith Type 1 diabetes mellitus (DM) (90-95%) compared to Type 1 DM. Interaction of metabolic and vascular factors are responsible for peripheral neuropathy.[10]

1.2.2. Clinical Features of DPN

Increased reaction time and decreased proprioception results in postural instability and balance impairments and because of patients with DPN face difficulty in maintaining balance even with eyes open resulting in more number of falls. [9,11] DPNhas been associated with long term disability due to foot ulcers and amputation, balance impairments, gait instabilities and injuries due to fall and 20-30% of patients with DPN experiences neuropathic pain[12](Figure 1.1). Sensory symptoms of DPN usually starts in the toes and with time progress to proximal parts of limbs and characterised as tingling, pins and needles sensation, allodynia, burning, electric shocks like sensation and hyperalgesia.[10] Dyslipidemia and reduced neuronal sensitivity are the major cause of DPN in patients with Type II DM whereas reduced level of both, insulin and C-peptide holds a significant cause for DPN.[10]

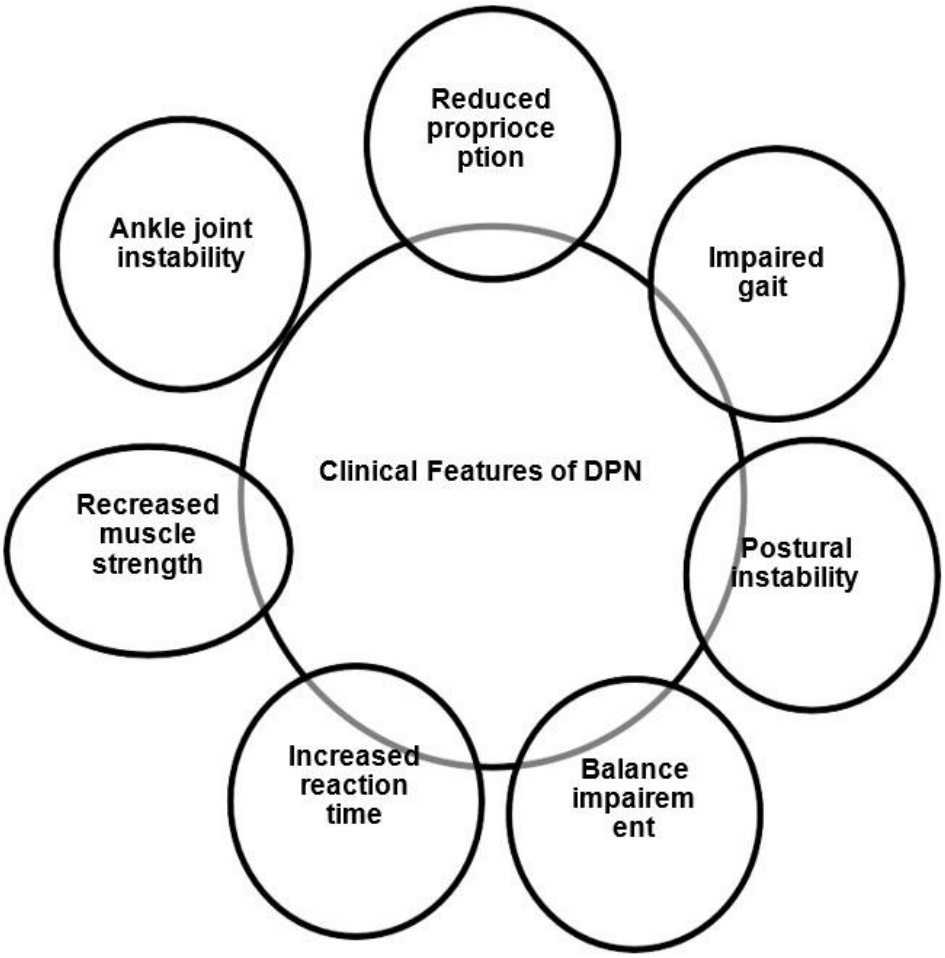

Figure 1.1: Clinical manifestations of DPN

1.2.3. Types of DPN

Involvement of peripheral nerves give rise to a broad classification of DPN based clinical manifestation and has classified into 3 types: Hyperglycaemic neuropathy, Symmetric polyneuropathy and focal and multifocal neuropathy (Figure 1.2).[13] Among all types of neuropathies, chronic distal symmetrical sensory-motor polyneuropathy being the most common and found in 50% of diabetic patients.[14]

Hyperglycemic neuropathy	Symmetric Polyneuropathy	Focal and multifocal neuropathy
• In this type of DPN patients shows reduced nerve conduction velocity which is shown to be improved with euglycemic agents	• More persistent type of DPN characterised as symmetrical distribution of signs and symptoms of DPN especially in hands and feet. • It is further divided into two types: • Sensory/autonomic polyneuropathy • Acute painful diabetic neuropathy	• This neuropathy affects the cranial nerve in which third, sixth and seventh cranial nerve being most affected. • Nerves of limbs and thoraco-abdominal are also involved in this neuropathy • Trunk involvement presents with girdle-like pain, with or without sensory involvement

Figure 1.2: Classification of DPN

1.2.4. Management of DPN

Management of DPN comprises a multidimensional approach broadly divided into pharmacological and non-pharmacological management (Table 1.1)

Table 1.1. Classification of management of DPN

Pharmacological management	**Non-Pharmacological management**
Anticonvulsants	Counselling
Tricyclic Agents	Physiotherapy
Selective Serotonin Reuptake Inhibitors (SSRIs)	Dietary Modification
Local Anaesthetic Arrythmic Agents	Yoga
Tropical nitrate	
Opioid Analgesics	
NMDA antagonists	

1.2.4.1. Pharmacological Management

Many therapeutic agents are used to manage symptoms of DPN. These agentswork by inhibiting presynaptic reuptake of serotonin[15](Table 1.2).

Table 1.2: Pharmacological agents for management of DPN

Drugs	Description
Tricyclic Agents[15]	Amitriptyline and imipramine are the first - line tricyclic agents used for the management of neuropathic pain, works by inhibiting reuptake of norepinephrine and serotonin. Mouth dryness, blurring of vision, cardiac arrythmias, disturbed digestion and postural hypotension are some side effects of these agents. 25-150 mg daily was proved to be effective in managing DPN.
Anticonvulsants[16]	Gabapentin is most effective drug used for the management of neuropathic pain. Dosage of 1.8g/day is shown to be effective for pain reduction. Sedation, headache, oedema of foot, weight gain and nausea are some side effects of these agents but these side effects are less as compared to tricyclic agents.
Local Anaesthetic arrhythmic Agents[16,17]	Lidocaine is most effective used sodium channel blocker that prevents central nervous system hyperexcitability. Intravenous Lidocaine are most effective than oral lidocaine. Difficulty breathing, chest pain, difficulty in swallowing, dizziness and blurring of vision are some serious side effects of local anaesthetic arrhythmic agents
Selective Serotonin Reuptake Inhibitors[18]	Paroxetine and Citalopram are most commonly SSRIs which work by inhibiting presynaptic reuptake of serotonin only. Use of upto 40mg/day dosage of SSRIs was found to be effective in managing the symptoms of DPN.
NMDA Antagonists[19]	Dextromethorphan and memantine are two commonly used NMDA antagonists for the management of DPN
Opioid Analgesics[20]	Tramadol and synthetic narcotic analgesic are effective opioid analgesics which can be used upto six months for the management of DPN. Sleeplessness, constipation, vomiting and nausea are some side effects of these agents. 50-400 mg of daily dose has shown effective relief from DPN Symptoms

Tropical Nitrate	Isosorbide is the one topical nitrate used for relieving pain and burning associated with DPN.

1.2.4.2. Non-Pharmacological Management of DPN

Non-pharmacological management has procured an importance in managing symptoms of DPN because of no side effects. Different types of non-pharmacological management have their own importance.

1.2.4.2.1. Counselling

After the establishment of diagnosis of DPN, counselling regarding the condition and its complications plays an extreme important role to combat DPN. patients with DPN are more vulnerable to have sensory impairments and foot ulcerations. Advice regarding foot care, footwear modification and techniques such as, use of a bed cradle to lift the skin from bed sheets are essential to cope up with hyperaesthetic skin plays an utmost role.[18]

1.2.4.2.2. Yoga

Sudarshan Kriya and yogic breathing exercises has shown to be beneficial in improving quality of life, postprandial plasma glucose and autonomic functions in patients with DPN.[21] Yoga has been found to reduce blood lipid levels and decrease in blood lactate.[22] Eight week of yoga, including breathing exercises, dynamic movements of trunk in sitting and standing, standing postures with progressive gradation with chair or wall support has found to improve balance, balance confidence and occupation performance in patients with DPN.[23] Twelve weeks of asana series including Vrikshasana, Tadasna, Padhastasana, Utkatasana, Virabhadrasana, Garudasana and Natrajasana were found to improve static and dynamic balance and lower limbs muscles strength.[24]

1.2.4.2.3. Dietary Modification

Dietary modification is the mainstay to manage bold glucose levels and prevention other associated complication such as, hypertension, high levels of low- density lipoprotein and total cholesterol in body.[22] Glycaemic level was found to be improved after 6 months of diet modification. Carbohydrate diet including type of sugar, amount of daily carbohydrate intake and source of starch. Fibre diet including colourful fruits, green vegetables and whole grains are proved to maintain glucose level in blood.[25]

1.2.4.2.4. Physiotherapy

Physiotherapy has been a boon for treatment of symptoms associated with peripheral neuropathies and role of physiotherapy in improving symptoms of DPN has gained an applaudable insight by reducing neuropathic pain[26], improved balance and proprioception[14] and increased muscular strength.[27] Various physiotherapy intervention used to treat DPN are shown in Figure 1.3.

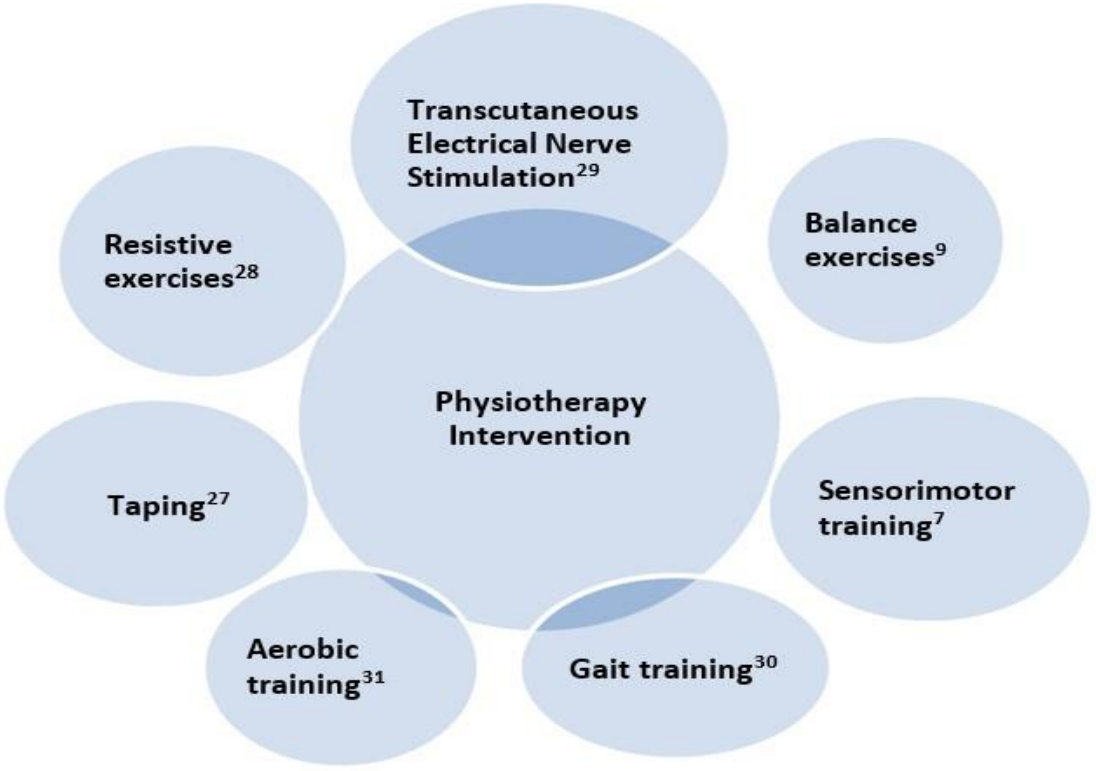

Figure 1.3: Various physiotherapy intervention for DPN

Taping, an emerging method of rehabilitation gaining popularity by providing many therapeutic effects such as, reduced pain, increased joint stability, improved body functions in athletes, as well in reducing recurrent injury[27]. Taping has been designed to mimic human skin qualities and is about the same thickness as the epidermis. Neuromuscular taping (NMT) has been used extensively to treat variety ofneurological and musculoskeletal conditions.[28] Previous literature has shown improved dorsiflexors strength after the application of K-tape on tibialis anterior, tibialisposterior and peroneus longus muscle in patients with DPN.[27] NMT is a technique of applying elastic adhesive tape to the skin without any tension over the target area which will create wrinkles in skin causing dilation effect on the underlying body tissue,thereby inducing pain relief, facilitation of lymphatic flow and increased vascularity[28]. NMT has found be effective in many conditions as shown in researches done on patients with multiple sclerosis[29], hemiplegia[30], and musculoskeletal disorders[31] but no study has been done with diabetes patients but no research has been done till dateto evaluate effect of neuromuscular taping on balance, proprioception, pain and nerveconduction in patients with diabetes peripheral neuropathy making it a significant gapin literature about effect of NMT in DPN.

1.3. Need of the Study

Physiotherapy has been an option for the management of DPN. There is plenty of literature available in treating DPN using various physiotherapeutic approach but there is scarcity of literature stating the effects of NMT for the management of DPN. NMT has emerged as an effective approach to treat musculoskeletal and neurological conditions but this concept has never been explored to treat balance, proprioception, pain and nerve conduction parameters in patients with DPN, thereby, making it the real need of time to explore.

1.4. Research Question

Does NMT proven to be an effective treatment in improving Balance, Proprioception, Pain and Nerve Conduction parameters in patients with DPN?

1.5. Aim of the Study

To estimate the effectiveness of NMT on Balance, Proprioception, Pain and Nerve Conduction parameters in patients with DPN.

1.6. Objectives

1.6.1. To determine the effect of NMTon Balance in patients with DPN.

1.6.2. To determine the effect of N M T on Proprioception in patients with DPN.

1.6.3. To determine the effect of NMT on Pain in patients withDPN.

1.6.4. To determine the effect of NMT on Nerve Conduction parameters in patients with DPN.

1.7. Research Hypothesis

1.7.1. Null Hypothesis (H_0) - There may be no significant effect of NMT in improving Balance, Proprioception, Pain and Nerve Conduction parameters in patients with DPN.

1.7.2. Alternate Hypothesis (H_A) - There may be a significant effect of NMT in improving Balance, Proprioception, Pain and Nerve Conduction parameters in patients with DPN.

1.8. Operational Definitions

1.8.1. Diabetic Peripheral Neuropathy: A disorder that damages peripheral nerves and induce neuropathic pain and symptoms for equal to or more than 5 yearsand scored more than 2/13 on physical appearance and greater than 1/10 on physicalexamination of Michigan neuropathy screening instrument (MNSI).

1.8.2. Neuromuscular Taping: A technique of applying elastic adhesive tape to the tibialis anterior, tibialis posterior, peroneus longus and medial arch of foot.

1.8.3. Balance: Ability of an individual to maintain their centre of gravity within their base of support and is impaired if score <45 on berg balance scale.

1.8.4. Proprioception: Ability of the body to sense position of body in space and the ability of move in forwards, backwards and sideways directions with eyes openand eyes closed in Pedalo®-Sensamove Balance Test Pro with Miniboard.

1.8.5. Pain: An unpleasant sensation that develops as a result of lesions or disease affecting the somatosensory nervous system either in the periphery or centrally and score >12 on Leads Assessment of Neuropathic Symptoms Scale (LANSS) scale.

1.8.6. Nerve Conduction Velocity: Speed at which electrochemical impulses propagates in tibial and peroneal nerves.

1.8.6.1. Nerve Conduction parameters: Measurement of latency, amplitude, and velocity of tibial and peroneal nerves.

. **1.8.6.2. H-reflex:** Reflectory reaction of muscles after electrical stimulation of sensory fibers of tibial and peroneal nerve.

2. Review of Literature

2.1. Introduction

This chapter will include the gathering of all the available literature stating the effects of physiotherapy in balance, proprioception, pain and nerve conduction parameters in patients with diabetic peripheral neuropathy. This literature review will allow to find the literature gap related to physiotherapy interventions for DPN and will help to fill the literature gap with new and emergent approaches in physiotherapy with the real need of time.

2.2. Search Strategy

PubMed/Medline, Ovid, Scopus, Cochrane Library and Physiotherapy Evidence database (PEDro) were searched to gather recent published literature stating the effects of physiotherapy in management of DPN. Searches were limited toEnglish literature only. Keywords used were (randomized controlled trial OR quasi-experimental study OR pilot study OR case study OR systematic review OR meta-analysis) AND diabetic peripheral neuropathy OR diabetic neuropathy) AND (physiotherapy OR rehabilitation OR balance exercises OR balance training OR proprioception exercises OR proprioception training OR exercise therapy OR electrotherapy OR transcutaneous electrical nerve stimulation (TENS)) AND (neuromuscular taping OR taping) AND Pedalo®-Sensamove Balance Test Pro with Miniboard) AND (neuropathic pain OR pain) AND (nerve conduction velocity OR nerve conduction study OR nerve conduction).

2.3. Diabetic Peripheral Neuropathy and Balance and Proprioception

Studies evaluated the effect of balance and proprioception training are displayed in Table 2.1.

Table 2.1: Balance and proprioception training in DPN patients

Authors/ Year	Aim	Methods	Outcome measures used	Results	Conclusion
El-Wishy et al. (2012)[32]	To investigate the effects of proprioceptive training program on sway indices and functional balance in diabetic peripheral neuropathy	28 diabetic patients aged 35-50 years, with diagnosed polyneuropathy of duration at least two years were equally divided into two groups. Proprioceptive group received conventional physiotherapy for 45 minutes of exercise along with additional 26 minutes of proprioceptive training. Control group received only 45 minutes of conventional physiotherapy	Balance was assessed using berg balance scale and Biodex balance system during bipedal stance with closed eyes before and after 8 weeks of intervention index (ML)	Significant decrease in the balance indices and significant increase in BBS scores were found after treatment in both control and proprioceptive training groups.	Proprioceptive training along with conventional physiotherapy was more effective in improving functional balance and reducing balance indices in diabetic neuropathy
Shiraz et al., (2016)[33]	To compare the effects of two therapeutic exercises on clinical balance measures in patients with type II diabetic peripheral neuropathy	Total of 60 DPN patients were divided equally into three groups. Intervention group received exercises with swiss ball in which training was given in 2 parts. In first part, patients	One leg stance was used to measure postural stability. Berg balance scale was used to assess functional balance and star excursion balance test was used to	Ball training group and Frenkel training group showed significant improvement in one leg stand, star excursion test and berg balance scale compared to control group. However, ball	Swiss ball training was found to be more effective in improving balance compared to Frenkel exercises and no exercise

		were asked to perform movement while sitting on a ball and in second part patients were asked to perform movement in standing while holding the ball in hands. Control group received no treatment and Frenkel exercise group received Frenkel exercise	assess dynamic balance	training group was improved more significantly	
Ahmad et al. (2019)[7]	To evaluate the effect of sensorimotor training on balance measures, and proprioception, among middle-aged and older adults with diabetic peripheral neuropathy	37 patients of DPN aged 45-75 years, divided into intervention group (N=8 for age < 60 years and N= 12 for age ≥ 60 years) and control group (N= 8 for < 60 years and N=9 for age ≥ 60). Intervention group received sensorimotor training for thrice a week for eight weeks along with diabetic foot care and subjects in control group received diabetic	Functional reach test was used to assess dynamic balance, timed up and go test to assess functional mobility, static balance to assess one leg stance. Postural assessment and proprioception were done using Pedalo®-Sensamove Balance Test Pro with Miniboard,	After intervention, one leg standing, eyes open and eyes close on both legs showed significant time effect ($p \leq 0.003$), Functional reach test, TUG, COP range, COP sway, and proprioception were found significantly improved	Sensorimotor training is an effective way to treat balance impairments associated with DPN

		foot care only	Utrecht, The Netherland.		

Abbreviations: TUG= Timed Up and Go test, COP=Centre of Pressure

2.4. Diabetic Peripheral Neuropathy and Taping

Neuromuscular taping has proved to be effective in improving peripheral circulation in patients with diabetic foot. NMT is defined as application of elastic adhesive tape to skin to provide a decompressive effect at the treated site which results in pain reduction, facilitation of lymphatic fluid and increased vascularity of skin.[28]

An observation study done on 5 patients with diabetic foot aimed to evaluate the could be possible role of NMT for the treatment of diabetic foot ulcers. Bates-Jensen Wound Assessment Tool (BJWAT) was used to assess wound healing at baseline and after 4 weeks of application of NMT. BJWAT score was found to be improved significantly after the application of NMT.[34]

2.5. Effects of Taping on Balance and Proprioception

Any instability at ankle joint can result in impaired balance and decreased sense of posture, thereby affecting gait and results in postural instability. Taping for unstable ankle has been well established in literature and is proved to improve balance, proprioception and gait instability by improving ankle joint stability.[35]

There is scarcity of literature stating effects of NMT on balance in patients with DPN. A study has found improved dorsiflexors strength after the application of k tape at ankle joint. [27]

Other studies found significant improvement in balance and gait parameters after the application of taping at ankle joint.[36] (Table 2.2)

Table 2.2 Effect of taping on balance and proprioception

Authors/ Year	Aim	Methods	Outcome measures used	Results	Conclusion
Ibrahim et al., (2020)[15]	To investigate the effect of Kinesio tape and resistive exercise on dorsiflexors functional performance in diabetic patients with peripheral neuropathy and compare between them	40 Type II diabetic patients, aged 50-60 years old were divided into 2 groups. Group A received resistance training and group B received resistance training	Muscle strength was assessed using hand held Dynamometer and functional capacity was assessed using 6-minute walk test	Group A showed significant improvement in the strength of right dorsiflexors and group B showed significant improvement in the strength of both dorsiflexors	Both Kinesio TM tape and resistive exercise improve the dorsiflexors and functional performance in diabetic polyneuropathy
Choi et.al (2020)[36]	To determine the immediate effects of ankle non-elastic taping on balance and gait ability in patients with chronic stroke	30 patients with stroke equally divided in 2 groups: non-elastic taping group and placebo taping group. Patients in the non-elastic taping group received taping at ankle joint and patients in the placebo-taping group received Endura fix tape at ankle joint	Balance was assessed by using the Balance System SD and gait was assessed by GAITRite system	The non-elastic taping group showed a significant improvement in balance, increases in velocity, cadence, step length, and stride length after intervention at P≥ .001 whereas placebo taping group showed no improvement in balance and gait ability after intervention (P >.05)	Application of ankle non-elastic taping is effective at improving balance and gait abilities in patients with stroke. Ankle non-elastic taping appears to be an effective method to facilitate active rehabilitation in patients with hemiplegia

2.6. Taping and Pain

NMT creates an eccentric force when applied to skin thereby facilitated sensorimotor and proprioceptive system. Application of NMT has been supposed to activate cutaneous mechanoreceptors, normalise functions of muscles, increase lymphatic and venous flow, reduction of pain and postural correction by relaxing the overused muscles.[37] Taping has been used to treat musculoskeletal conditions, such as, osteoarthritis[38], myofascial pain syndrome[39], patellofemoral pain syndrome[40], pain[37] and decreased range of motion[38] No study can be found to evaluate the effect of NMT on pain reduction in DPN patients. (Table 2.3)

Table 2.3: Effect of taping on pain

Authors/ Year	Aim	Methods	Outcome measures used	Results	Conclusion
Berlingieri et al., (2016)[37]	To evaluate the possible application of Neuromuscular Taping (NMT) in subjects with MS in order to reduce pain in comparison to other two common treatments.	15 patients with multiple sclerosis were divided into 3 groups. Control group received physical rehabilitation program, NMT group received NMT along with physical rehabilitation and TENS group received TENS	Visual analogue scale and Neuropathic pain scale were used to assess pain Performance Oriented Mobility Assessment (POMA) scale was used to assess balance	All three groups showed significant improvement in POMA, NRS and VAS after intervention	NMT together with standard physical rehabilitation was able to reduce neuropathic pain to greater lengths

2.7. Diabetic Peripheral Neuropathy and TENS

Studies that evaluated the effect of TENS in patients with DPN are depicted in Table 2.4.

Table 2.4: Application of TENS in DPN

Authors/ Year	Aim	Methods	Outcome measures used	Results	Conclusion
Bulut et.al., (2010)[26]	To compare the efficacy of TENS and placebo TENS in the treatment of DPN	40 patients with DPN, divided into 2 groups: TENS group (n=20) and Placebo TENS group (n=20) To TENS group, stimulation was given at bilateral lumbosacral region, 3cm lateral to vertebral column with 80Hz for 30 minutes daily and for 20 days. No stimulation was given to sham TENS group	VAS was used to score pain	TENS group showed significant reductionin pain compared to Placebo group	TENS can be used as an effective measure to treat pain related to DPN without any side effect
Nabi et al., (2020)[41]	To compare the efficacy of treatment by DLX and TENS in diabetic peripheral neuropathy pain relief	60 DPN patients aged over 18 years, divided into two groups: DLX group and TENS group. DLX group received DLX (20, 40 and	Numeric pain rating scale was used to score pain before and after intervention	The NRS scores were significantly lower in DLX group however, no patients in TENS group reported any	DLX was found to be more effective than TENS but in condition of drug intolerance or contraindications, TENS could be more effective option to treat pain

		60mg/day for weeks 1,2, and 3-12 respectively) and TENS group received (TENS for 20minutes with 80HZ, 50 Amp, 0.2ms square pulses 2-3 times sensory threshold)		side effect whereas 18% patients in DLX reported side effects of DX.	
Bose et al., (2021)[3]	To find whether the TENS is effective for chronic painful diabetic neuropathy in case of Type 2 diabetes mellitus	Total 45 patients with DPN were equally divided into 3 groups. Group A received only medication as prescribed by physician, Group B received medication and TENS, Group C received medication and SHAM TENS. Parameters of TENS were: 2-70Hz, biphasic waveform, 4ms pulse width, >35mA intensity and for 40 minutes	VAS was used to assess pain before and after treatment	Group A showed significant reduction in pain compared to group B and group C	TENS reduces pain and discomfort of chronic painful diabetic neuropathy

Abbreviation: DLX= Duloxetine

2.8. Taping and Nerve Conduction Velocity

Nerve conduction velocity is a gold standard to assess the presence of peripheral neuropathies. Increased latency, reduced amplitude and nerve conduction velocity indicates the presence of peripheral neuropathies. Application of tape to painful area provides tactile stimulation to the skin which facilitates the excitability of the central nervous system and enhances the nerve conduction. A study showed significant decrease in latency and amplitude and increase in nerve conduction velocity in median ulnar and radial nerve after taping the volar aspect of hand in healthy individuals making it a need to explore the effect of taping in diseased population.[42] (Table 2.5)

Table 2.5: Effect of taping on nerve conduction velocity

Authors/ Year	Aim	Methods	Outcome measures used	Results	Conclusion
LEE et .al., (2011)[42]	To find out the effect of KT on the excitability of motor neuron	KT was placed on the volar side of the forearm. First, KT was cut according to the length of each participant's forearm, then applied while the participant's radiocarpal articulation was in maximum extension, beginning from the distal end and ending at the proximal end.	All participants had their latency, amplitude and motor nerve conduction velocity measured before the application of KT	After taping, latency and amplitude of median nerve and radial nerve was found to be slightly reduced and nerve conduction velocity was found to be increased whereas latency, amplitude and nerve conduction velocity of ulnar nerve was found to be increased.	Latency and amplitude of the median nerve after taping was slightly reduced and NCV was slightly increased. latency, amplitude and NCV of the ulnar nerve after the taping showed slight increases, Values of latency, amplitude and nerve conduction velocity of the ulnar nerve after the taping showed slight increases

2.9. Reliability, validity and Psychometric property of outcome measures

2.9.1. Berg Balance Scale

A scale to assess functional balance in older individuals and various neurological conditions including DPN. It comprises 14 items that assess static as well as dynamic balance. Maximum score of the scale is 56 and a score of <45 indicates high risk of falls. A study done on 5 diabetic patients to find test-retest reliability of BBS found good test-retest reliability with mean of 34.60 and SD ± 7.82 and 38.80 with SD± 1.28. Inter-rater reliability of ICC = 0.97 (95% CI 0.96 to 0.98) and intra-rater reliability of ICC= 0.98 (95% CI 0.97 to 0.99). The absolute reliability of BBS varies across the scale, with minimal detectable change with 95% confidence varying between 2.8/56 and 6.6/56.[43 44,45]

2.9.2. Pedalo®-Sensamove Balance Test Pro with Miniboard

A valid and reliable tool to assess balance and proprioception in patients with DPN. Instrument assess centre of sway and centre of pressure (COP) range. COP range is measured in four directions; front, back, left and right. To measure COP range subjects are asked to shift their COG while focusing on the screen by movement of the cursor from the centre. Subjects are asked to tilt maximally in four directions (front, back, left and right) and to hold the position for at least 3 seconds. The maximal tilt angle was recorded as COP range in each direction. To assess centre of sway requires subjects are instructed to look forwards while maintaining erect standing and focusing on the screen which is giving visual feedback to maintain the position of the marker within centrally positioned target box. Subjects are asked to maintain upright position for 30 seconds.[7]

Instrument is having good construct validity and the change in the COP range and COP sway showed moderate to high effect size (0.73 to 0.93) and standardized response mean (0.827 to 1.38).[46]

2.9.3. Leeds Assessment of Neuropathic Symptoms and Sign

A valid and reliable tool to assess presence of neuropathic pain. Scale is having discriminant validity as it is able to correctly identify between 73% and 75% of pain types. Relationship between each item of LANSS score and total score was found to

be positive, resulting in good construct validity of scale. The Cronbach alpha value for scale was 0.81 making its good internal consistency. [47]

2.9.4. Michigan Neuropathy Screening Instrument

A tool to assess neuropathic pain in patients with DPN with 79% sensitivity and 65% specificity with good validity and excellent internal consistency ICC= 0.80. [48]

3. METHODOLOGY

3.1. Study Design

Two group pretest posttest randomized sham- controlled trial

3.2. Study Location

Recognised tertiary care super speciality hospital

3.3. Study Setting

Neurological Physiotherapy Research lab

3.3. Study Participants

Individuals with Diabetic Peripheral Neuropathy of lower limbs

3.4. Sampling Method

Purposive sampling

3.5. Procedure

3.5.1. Ethical Statement

Ethical clearance will be obtained from Institutional Ethical Committee, Maharishi Markandeshwar (Deemed to be University). Guidelines of Declaration of Helsinki (2013) and National Ethical guidelines for the Biomedical and Health Research involving Human participants given by Indian Council of Medical Research (2017) will be followed for the study.[48]

3.5.2. Recruitment and Allocation

Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines[49] will be followed to conduct the trial (Figure 3.1). The results obtained from the trial will be return considering the CONsolidated Standards of Reporting Trials for non-pharmacological trials (Modified CONSORT), and the checklist, template for intervention, description, and replication (TIDieR). Individuals with DPN will be selected according to predefine selection criteria. Participants meeting the inclusion criteria will be included in the study. Data will be Procedure of the study willbe explained prior to the intervention and both English (Annexure II) and Hindi (Annexure III) written informed consent will be obtained from all participants. Outcome measurements will be taken at baseline, at 4 week and after completion of interventionat 8 week.

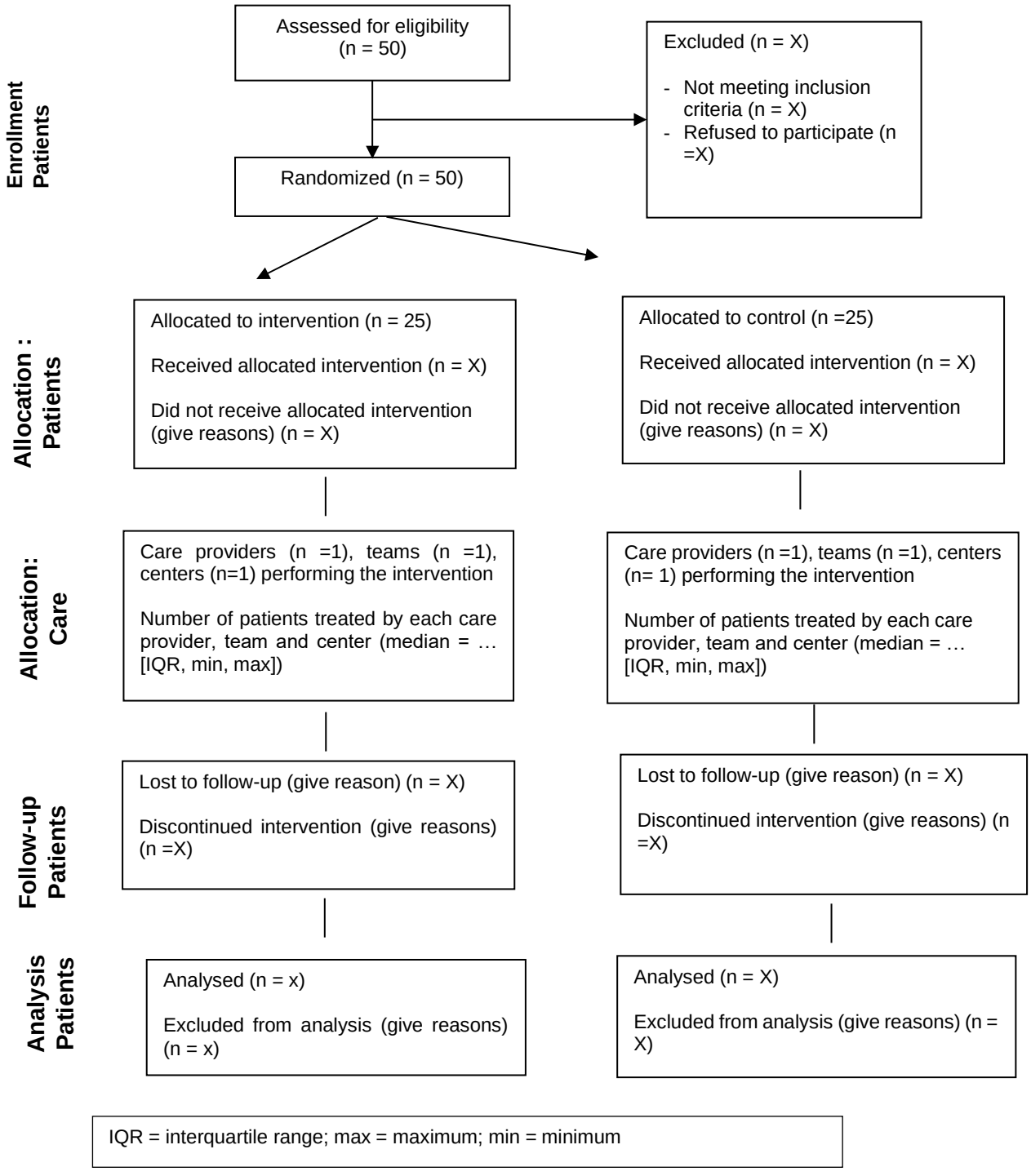
Enrollment Patients
Assessed for eligibility (n = 50)
Excluded (n = X)
- Not meeting inclusion criteria (n = X)
- Refused to participate (n =X)
Randomized (n = 50)
Allocation : Patients
Allocated to intervention (n = 25)
Received allocated intervention (n = X)
Did not receive allocated intervention (give reasons) (n = X)
Allocated to control (n =25)
Received allocated intervention (n = X)
Did not receive allocated intervention (give reasons) (n = X)
Allocation: Care
Care providers (n =1), teams (n =1), centers (n=1) performing the intervention
Number of patients treated by each care provider, team and center (median = … [IQR, min, max])
Care providers (n =1), teams (n =1), centers (n= 1) performing the intervention
Number of patients treated by each care provider, team and center (median = … [IQR, min, max])
Follow-up Patients
Lost to follow-up (give reason) (n = X)
Discontinued intervention (give reasons) (n =X)
Lost to follow-up (give reason) (n = X)
Discontinued intervention (give reasons) (n =X)
Analysis Patients
Analysed (n = x)
Excluded from analysis (give reasons) (n = x)
Analysed (n = X)
Excluded from analysis (give reasons) (n = X)
IQR = interquartile range; max = maximum; min = minimum

Figure 3.1: SPIRIT Flow chart of study participants

3.5.3. Sample Size

Sample size estimation is done by G*Power 3.1.9.4 software (Heinrich-heine-Universität Düsseldorf, Germany)[50] using effect size of included outcome measuresused in previous studies, 5% Level of Significance, 95% power and considering a dropout rate of 20%. Sample size calculation using BBS scale is more appropriate so the included total sample size for this study will be 50 (Table 3.1).

Table 3.1: Sample size estimation

Outcome Measure	Effect Size*	Calculated sample size	Estimated sample size
BBS (Figure 3.2)	1.17	42	50
LANSS (Figure 3.3)	1.5	28	32
NCV (Figure 3.4)	3.25	8	10
Pedalo Sensa Move (Right) (Figure 3.5)	1	58	70
Pedalo Sensa Move (Left) (Figure 3.6)	2.38	14	16
Pedalo Sensa Move (Front) (Figure 3.7)	1.02	56	67
Pedalo Sensa Move (Back) (Figure 3.8)	2.38	8	10

*Formula for effect size calculation: Pre Mean-Post Mean/d, where d= $\sqrt{(Sd^1)+(Sd^2)/2}$

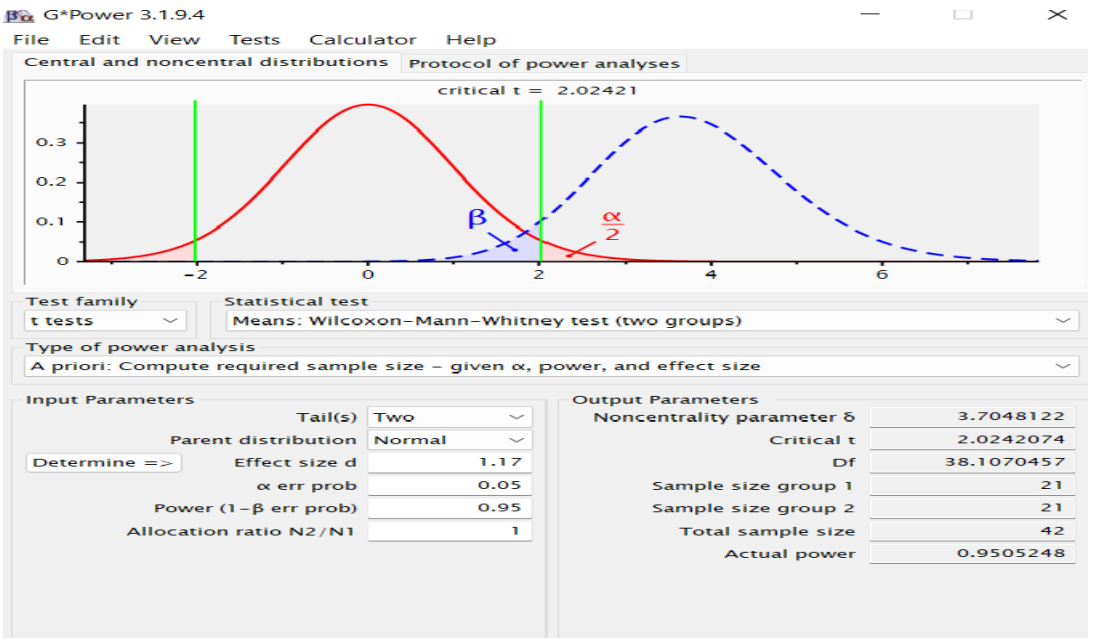

Figure 3.2: Sample size calculation using BBS

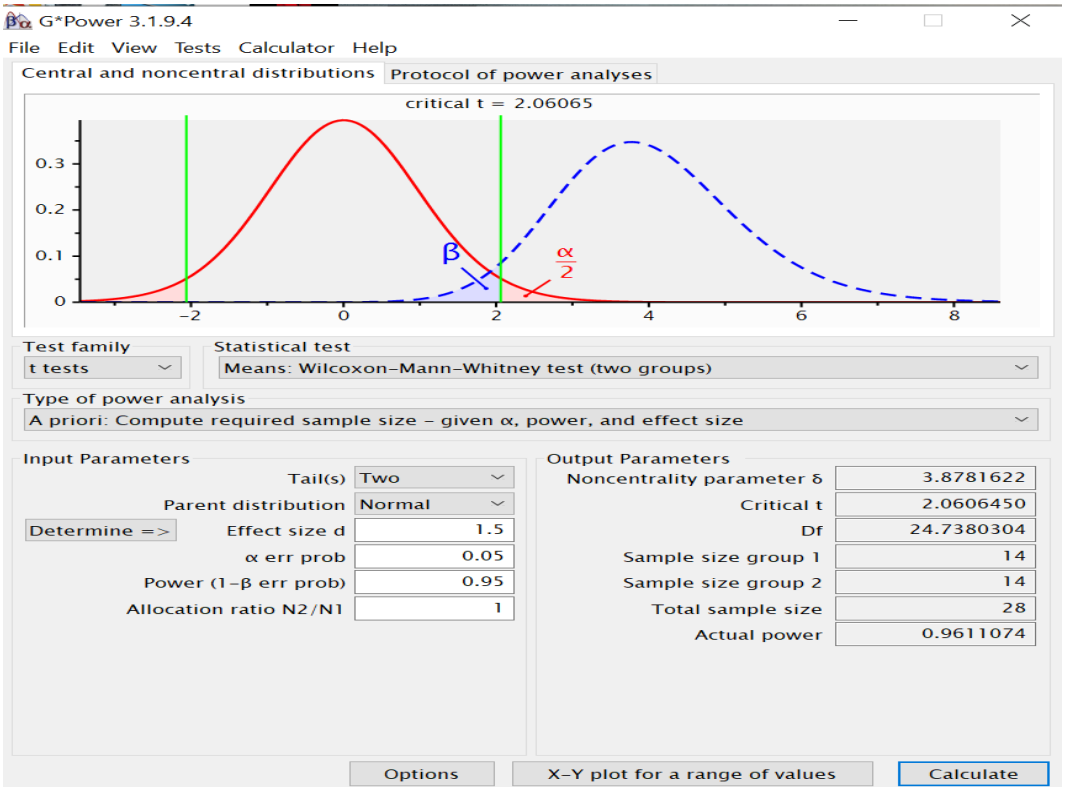

Figure 3.3: Sample size calculation using LANSS

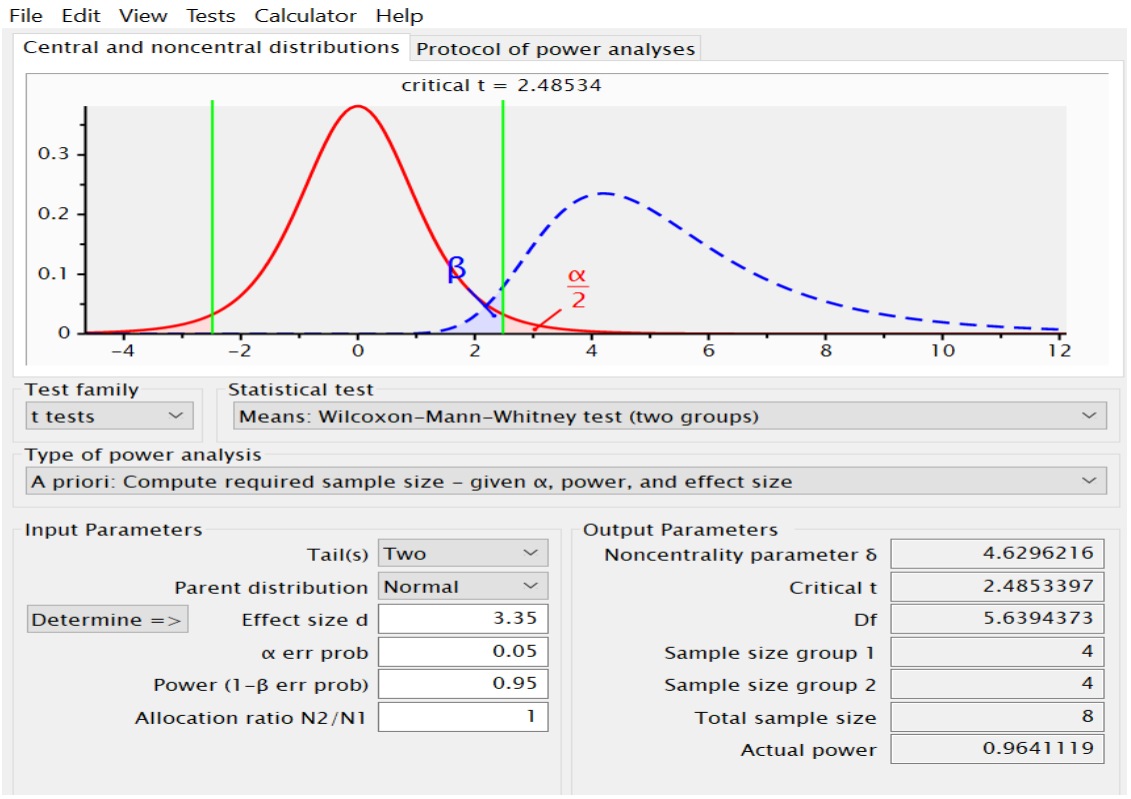

Figure 3.4: Sample size calculation using NCV

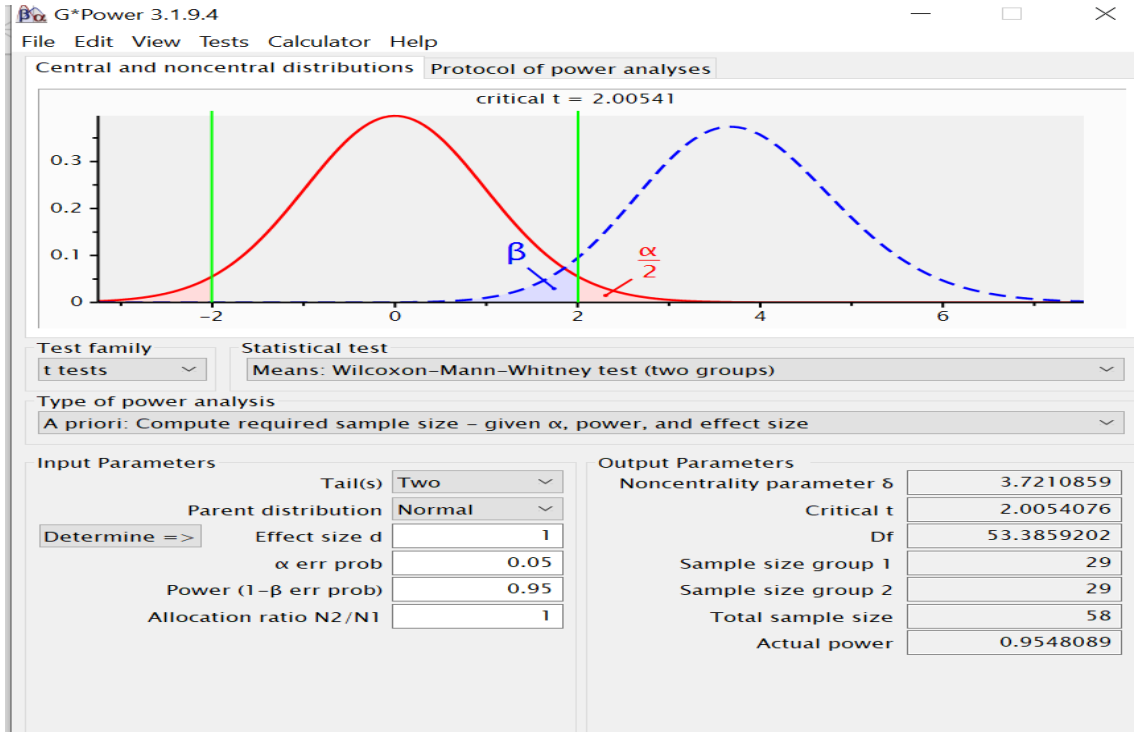

Figure 3.5: Sample size calculation using Pedalo Sensa Move (Right)

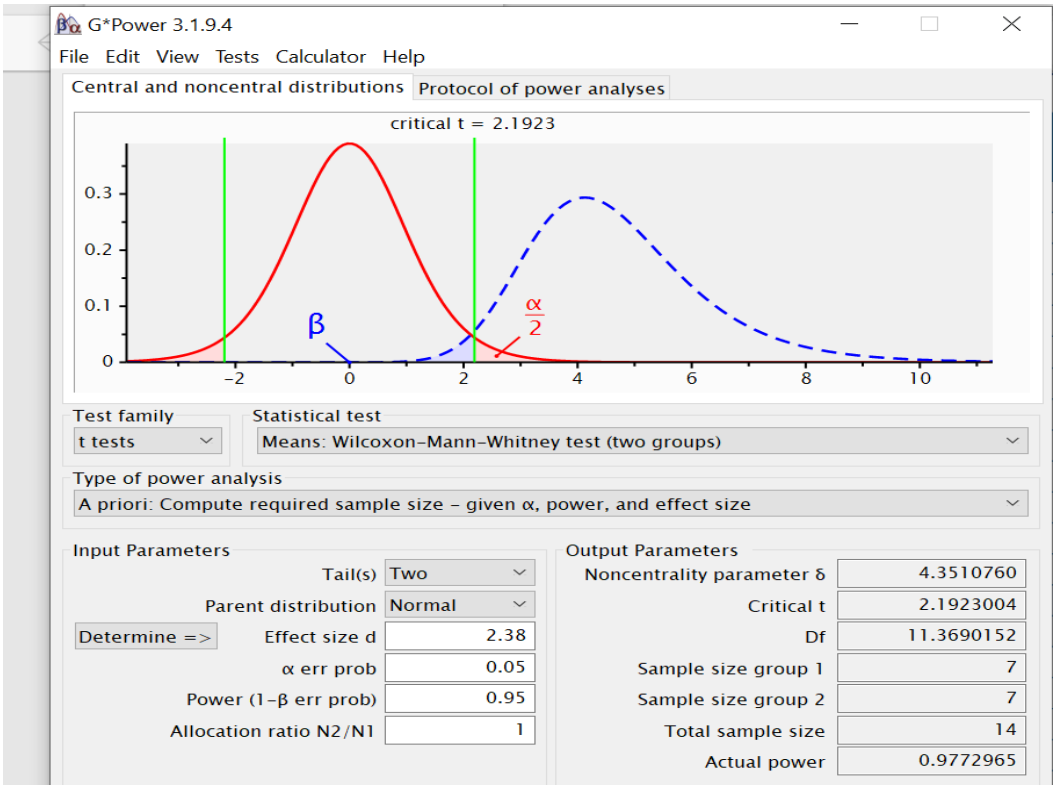

Figure 3.6: Sample size calculation using Pedalo Sensa Move (Left)

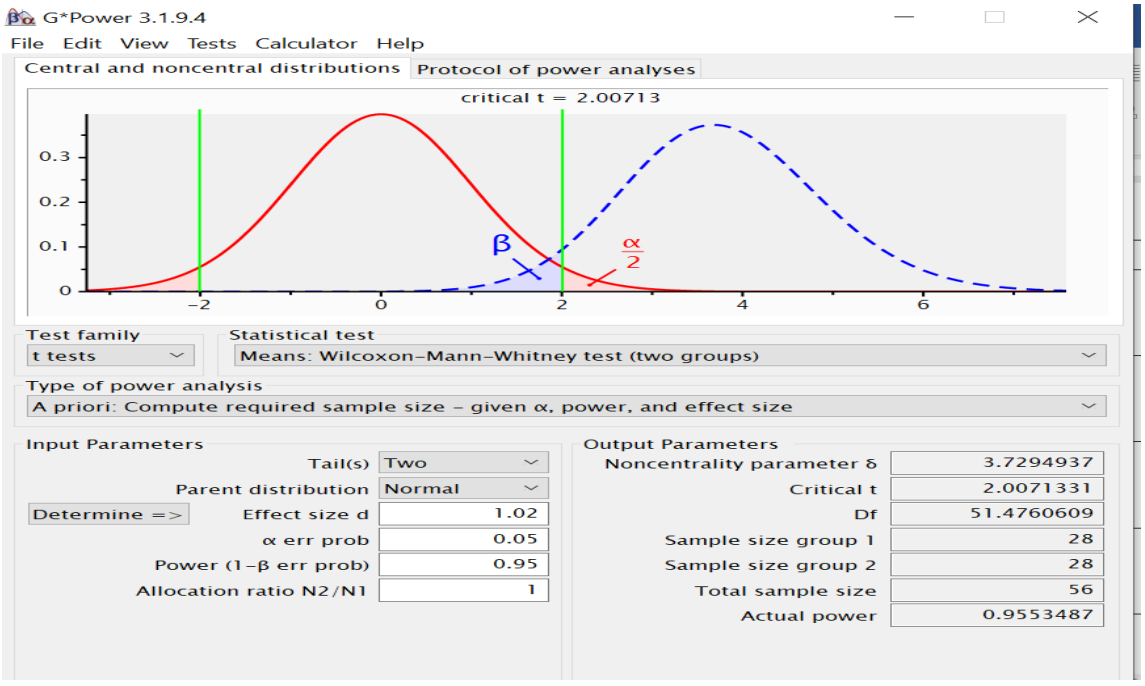

Figure 3.7: Sample size calculation using Pedalo Sensa Move (Front)

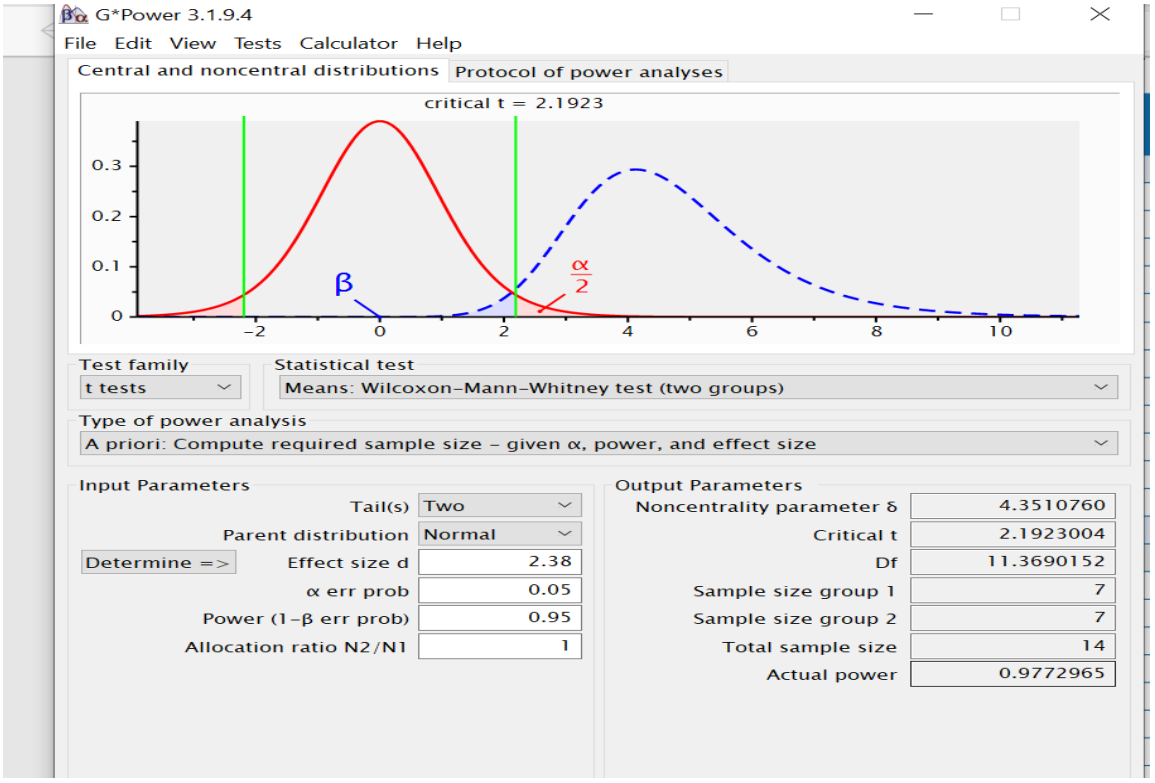

Figure 3.8: Sample size calculation using Pedalo Sensa Move (Back)

3.5.4. Randomisation and Blinding

Patients will be equally divided into two groups: EG (N=25) and CG (N=25) using manual block randomization method. The randomisation scheme will be based on a block randomization procedure and participants will be allocated toeither an experimental group and control group. As, the sample size of this study is 50, therefore there will be four blocks with matrix design 13×4 in which there will be only 2 columns in the last row as shown in Figure 3.9. Allocation concealment will be done by sequentially numbered opaque sealed envelopes (SNOSE). This will be a single blinded study in which assessor will be blinded for measurement of nerve conduction parameters.

Rows	EG	CG	EG	CG
1	•	•	•	•
2	•	•	•	•
3	•	•	•	•
4	•	•	•	•
5	•	•	•	•
6	•	•	•	•
7	•	•	•	•
8	•	•	•	•
9	•	•	•	•
10	•	•	•	•
11	•	•	•	•
12	•	•	•	•
13	•	•		

Figure 3.9: Block randomization of participants

3.5.5. Selection Criteria

3.5.5.1. Inclusion criteria

3.5.5.1.1. Both males and females

3.5.5.1.2. Referred cases of Type 1 & Type 2 diabetes mellitus induced diabetic peripheral neuropathy of lower limbs diagnosed by physician and score more than 2/13 on MNSI physical appearance section and scored greater than 1/10 on physical examination of Michigan neuropathy screening instrument (MNSI)

3.5.5.1.3. Diabetes duration: ≥5 years

3.5.5.1.4. Age between 40 to 70 years

3.5.5.1.5. Chronic symmetric sensorimotor involvement of bilateral lower limb after excluding all other causes of peripheral neuropathies

3.5.5.1.6. Leeds Assessment of Neuropathic Symptoms Scale (LANSS) score > 12

3.5.5.1.7. Berg Balance Scale (BBS)<45

3.5.5.1.8. HbA1C report ≥6% not older than 3 months

3.5.5.1.9. Willing to participate

3.5.5.1.10. BMI <30kg/m^2 (According to Asian criterion) (Annexure VIII)

3.5.6. Exclusion Criteria

3.5.6.1. Allergic to tape

3.5.6.2. Any other diagnosed neuromuscular disease

3.5.6.3. Vestibular system dysfunction in the last one year (complaint of

dizziness, vertigo, nausea and loss of balance)

3.5.6.4. Diabetic foot ulcers, neuropathic joint, charcot joint

3.5.6.5. History of any recent injury (soft tissue and bony) in lower limb six months prior to participation in study

3.5.6.6. Patients with rheumatoid arthritis

3.5.6.7. Patients with varicose veins

3.5.6.8. Fixed ankle contractures

3.5.6.9. Any other cause of balance and gait disturbance

3.5.6.10. Deformities of lower limb

3.5.6.11. Patients with leg length discrepancy

Outcome Measures

3.5.6.1. Berg Balance Scale (BBS)

It is a reliable functional scale which is used to assess balance impairments in elderly and various neuromuscular conditions. Scale contains 14 items which assess static and dynamic balance. Each item is scored on a five-point Likert scale (0-4) according to the quality or duration of the task. Maximum score of the scale is 56 and a score of <45 indicates high risk of falls.[44]

3.5.6.1. Pedalo®-Sensamove Balance Test Pro with Miniboard

Proprioception will be measured using Pedalo®-Sensamove Balance Test Pro with Miniboard. It is used to measure proprioception, balance, reaction time and coordination.[52]

3.5.6.2. LANSS Pain Scale

LANSS Pain Scale is used to distinguish patients with neuropathic pain from those with nociceptive pain. Scale has two sections: Pain questionnaire and sensory testing. Participants are asked about how their pain has felt over the past week and responses were obtained in Yes or No only. Cronbach's alpha value is 0.76 for the total LANSS score. Cut of ≥12 indicates presence of neuropathic symptoms.[51]

3.5.6.3. Nerve Conduction Velocity (NCV)

The most accurate, reliable and sensitive measure to assess functioning of peripheral nerves.[53] For this study, nerve conduction study of common peroneal nerve, tibial nerve and sural nerve will be done by using Neuropack S3 MEB-9600 V02-03 (C) 2018 Nihon Kohden Co. Nerve conduction velocity of tibial nerve and peroneal nerve will be done.

3.5.6.4. Michigan Neuropathy Screening Instrument

A valid and reliable tool to assess presence of DPN. It has 2 sections: physical appearance and physical examination. Each item of physical appearance section grade as Yes or No and each item of physical examination grade as present or absent. Score ranges from 0 to 8.[47]

3.5.7. Variables

3.5.7.1. Dependent Variables

3.5.7.1.1. Balance (static and dynamic)

3.5.7.1.2. Proprioception

3.5.7.1.3. Pain

3.5.7.1.4. Nerve Conduction parameter

3.5.7.2. Independent Variables

3.5.7.2.1. Neuromuscular Taping (NMT)

3.5.7.2.2. Transcutaneous Electrical Nerve Stimulation (TENS)

3.5.7.2. Materials to be used

Stationaries, electrodes, gel, tape

3.5.8. Interventions

Participants will be divided in two groups: EG and CG. EG will be treated with NMT and TENS and CG will be treated with ShamNMT and TENS. Intervention will be

given 3 times a week for 8 weeks (24 sessions).NMT will be done at first day and will be replaced at 3rd day of every week.[35] Intervention for EG and CG are given in Table 3.2 & 3.4.

Table 3.2: Intervention for EG

NMT	TENS
NMT will be done at tibialis posterior, tibialis anterior, peroneus longus muscles and medial arch of foot. For tibialis posterior, patient will be in prone position with the foot hanging off in a relaxed position. First strip of tape will be applied from the origin to the insertion of the posterior tibialis muscle. For taping at tibialis anterior muscle participant will lay supine on the treatment table and the second strip will be applied from the origin to the insertion of the tibialis anterior muscle. For peroneus longus muscle and medial arch of foot, patient will lay in supine position and the third strip will be applied from the origin to the insertion of the peroneus longus muscle. The fourth strip will begin just anterior to the lateral malleolus, extended under the plantar aspect of the foot, and will pulled up the transverse arch of the foot. (Figure 3.10)	TENS will be applied at distribution of tibial nerve and peroneal nerve. For tibial nerve one electrode will be placed over the proximal tibia and other electrode will be placed over the ankle. patients will receive 10 sessions of TENS (80 Hz, 50 Amp, 0.2 ms square pulses, 2 to 3 times sensory threshold) every alternate day for 3 weeks for 20 min, with one electrode placement over the proximal tibia and other electrode over the ankle.[53] For peroneal nerve one electrode will be placed just below the head of the fibula and other electrode will be placed at ankle joint.[54] (Figure 3.11)

Figure 3.10: Application of NMT 3.10(A):

3.10 (A): Tibialis Anterior muscle

3.10 (B): Peroneus Longus muscle

3.10(C): Tibialis Posterior muscle

3.10 (D): Transverse arch of foot

Figure 3.11: Application of TENS

3.11(A): Peroneal Nerve

3.10 (B): Tibial Nerve

Table 3.3: Intervention for Control group

Sham NMT	TENS
Sham NMT will be done at ankle joint without any tension in tape. (Figure 3.12)	TENS will be applied at distribution of tibial nerve and peroneal nerve. For tibial nerve one electrode will be placed over the proximal tibia and other electrode will be placed over the ankle. patients will receive 10 sessions of TENS (80 Hz, 50 Amp, 0.2 ms square pulses, 2 to 3 times sensory threshold) every alternate day for 3 weeks for 20 min, with one electrode placement over the proximal tibia and other electrode over the ankle.[53] For peroneal nerve one electrode will be placed just below the head of the fibula and other electrode will be placed at ankle joint.[54] (Figure 3.11)

Figure 3.12: Sham taping

4. Data analysis

Data will be analysed using statistical software, statistical package for social science (SPSS), IBM SPSS. The collected demographics and outcome measures will be assessed for their normality using Kolmogorov- Smirnov test. Demographics will be expressed in descriptive statistics. Repeated measures ANOVA/Friedman test will be chosen based on normality to find differences within group at 4^{th} week (follow up) and 8^{th} week (completion). Paired t test/ Wilcoxon signed rank test will be chosen to find differences between group for pre-post intervention changes in outcome measures. Independent t test/ Mann- Whitney U- test will be chosen based on normality to compare the changes in mean values of the outcome measures between experimental group and control group at baseline, 4^{th} week and 8^{th} week of intervention.

5. Discussion

Diabetic peripheral neuropathy has been a major cause of disability due to complications associated with it. Early diagnosis and interventions are necessary to prevent long term disability. Many physiotherapeutic interventions have been proved effective to treat DPN. Neuromuscular taping is emerging as a new tool to treat variety of musculoskeletal and conditions neurological but very few work is done with taping in peripheral neuropathies so making it a demand of time to evaluate the effect of NMT on balance, proprioception, pain and nerve conduction velocity in patients with diabetic peripheral neuropathy.

5.1. Strength of the study

- Study design
- Use of strong and effective outcome measures
- Inclusion of both, tibial and peroneal nerve

5.2. Limitations

- Unavoidable human error

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Annexure I

Data Collection Form

Name –

Age (years) –

Gender –

Height

(cm) –

Weight (kg)

–BMI

(kg/m^2) –

HBA1C

(%)-

Duration of diabetes (in years)-

Outcome Measures-

Outcome Measure	Experimental Group			Control Group		
	Baseline	4th Week	8th Week	Baseline	4th week	8th Week
BBS Score						
Proprioception (Right)						
Proprioception (Left)						
Proprioception (Front)						
Proprioception (Back)						

LANSS score						
Motor NCV(m/s)						
Sensory NCV(m/s)						
H-reflex						

Annexure II

Consent Form (English)

This Informed Consent Form is for individuals who will attend the research project conducted at MMIPR, the title of our research project is “Effectiveness of Neuromuscular Taping on Balance, Proprioception, Pain and Nerve Conduction parameters in patients with Diabetic Peripheral Neuropathy”

Name of Organization: Maharishi Markandeshwar (Deemed to be University)

Name of Sponsor: Nil

This Informed Consent Form has two parts:

- Information Sheet (To share information about the research with you)
- Certificate of Consent (For signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

Annexure II (a)

Information sheet (English)

I, Kanika, Ph.D. Scholar, MMIPR is conducting research to find the Effectiveness of Neuromuscular Taping on Balance, Proprioception, Pain and Nerve Conduction parameters in patients with Diabetic Peripheral Neuropathy. I will give you all detailed information about our research and invite you to participate in our research project. You can take your own time to think whether you will participate or not and you can talk to anyone you feel comfortable about the research.

This study will be conducted as part of my Ph.D. thesis. If you have question about this research, you can ask me or supporting staffs associated with this study.

Prior to your participation, an investigator will take your brief medical history to determine your disease and problem, which would make you eligible to participate. You will be asked to provide general information about yourself age and few general parameters will also be recorded. You will be assigned a subject number so that your name will not be associated with any of the findings of the study. Your participation in this research is voluntary. It is your choice whether to participate or not. If you don't want to participate in this research you will be offered treatment that is routinely given for patients with DPN. You have the right to withdraw from the study at any time. We will allocate all the participants in one single group. All the participants will receive neural mobilizations of lower extremities. We will take pre-test and post-test assessment using some scales and Pedalo sensa move balance miniboard. Treatment protocol will continue for 8 weeks, after that we will record your balance, proprioception, pain and nerve conduction velocity again to see the pre-test and post-test improvement.

The risk of participation in this study is minimal and there will be no side effect of our intervention. To assure safety of the participant, loud and clear instruction will be administered. One staff will stand near the subject for ensuring safety. We cannot be able to pay you for your travelling and participation because our project is not funded. The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what

your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone. The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Annexure II (b)

Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date_____(Day/month/year)

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

Annexure 3(a)

Consent Form (Hindi)

सूचित सहमति फॉर्म (WHO- प्रारूप):

परिशिष्ट 1

सूचित सहमति प्रपत्र (ICF)

यह सूचित सहमति फॉर्म उन व्यक्तियों के लिए है जो MMIPR में आयोजित अनुसंधान परियोजना में भाग लेंगे, हमारी शोध परियोजना का शीर्षक है : "मधुमेह परिधीय न्यूरोपैथी के साथ रोगियों के बीच संतुलन, प्रोप्रियोसेप्शन, दर्द और तंत्रिका चालन पर न्यूरोमस्कुलर टैपिंग की प्रभावशीलता।

संगठन का नाम: महर्षि मार्कंडेश्वर (डीम्ड यूनिवर्सिटी)

प्रायोजक का नाम: शून्य।

यह सूचित सहमति फॉर्म के दो भाग हैं:

• सूचना पत्र (आपके साथ अनुसंधान के बारे में जानकारी साझा करने के लिए)

• सहमति का प्रमाण पत्र (हस्ताक्षर के लिए यदि आप भाग लेने के लिए सहमत हैं)

आपको पूर्ण सूचित सहमति फॉर्म की एक प्रति दी जाएगी।

सहमति का प्रमाण पत्र

मैंने पूर्वगामी जानकारी पढ़ी है, या यह मुझे पढ़ी गई है। मुझे इसके बारे में प्रश्न पूछने का अवसर मिला है और जो भी प्रश्न मैंने पूछे हैं उनका उत्तर मेरी संतुष्टि के लिए दिया गया है। मैं स्वेच्छा से इस शोध में एक भागीदार के रूप में भाग लेने के लिए।

प्रतिभागी का नाम प्रिंट करें _____

प्रतिभागी का हस्ताक्षर _____

दिनांक _____

दिन महीने साल

अगर अनपढ़ है

मैंने संभावित प्रतिभागी को सहमति फॉर्म के सटीक पढ़ने को देखा है, और व्यक्ति को सवाल पूछने का अवसर मिला है। मैं पुष्टि करता हूं कि व्यक्ति ने स्वतंत्र रूप से सहमति दे दी है।

गवाह का नाम _____ और प्रतिभागी का अंगूठा प्रिंट

गवाह के हस्ताक्षर _____

दिनांक _____

दिन महीने साल

सहमति लेने वाले शोधकर्ता / व्यक्ति का कथन

मैंने संभावित प्रतिभागी को सूचना पत्र को सटीक रूप से पढ़ा है, और मेरी पूरी क्षमता से यह सुनिश्चित हो गया है कि प्रतिभागी समझता है कि निम्नलिखित किया जाएगा:

१।

२।

३।

मैं इस बात की पुष्टि करता हूं कि प्रतिभागी को अध्ययन के बारे में सवाल पूछने का मौका दिया गया था, और प्रतिभागी द्वारा पूछे गए सभी सवालों का सही और मेरी सर्वश्रेष्ठ क्षमता पर जवाब दिया गया है। मैं इस बात की पुष्टि करता हूं कि व्यक्ति को सहमति देने के लिए बाध्य नहीं किया गया है, और सहमति स्वतंत्र रूप से और स्वेच्छा से दी गई है।

इस ICF की एक प्रति प्रतिभागी को प्रदान की गई है।

सहमति लेने वाले शोधकर्ता / व्यक्ति का नाम

सहमति लेने वाले शोधकर्ता / व्यक्ति का हस्ताक्षर _____

दिनांक _____

दिन / महीने / साल

Annexure 3 (b)

सूचना पत्र

मैं MMIPR में पीएचडी विद्वान की **छात्रा** कनिका। हम "मधुमेह परिधीय न्यूरोपैथी के साथ रोगियों के बीच संतुलन, प्रोप्रियोसेप्शन, दर्द और तंत्रिका चालन पर न्यूरोमस्कुलर टैपिंग की प्रभावशीलता खोजने के लिए एक शोध कर रहे हैं।मैं आपको हमारे शोध के बारे में सभी विस्तृत जानकारी दूंगी और आपको हमारी शोध परियोजना में भाग लेने के लिए आमंत्रित करूंगी। आप यह सोचने के लिए अपना समय ले सकते हैं कि आप भाग लेंगे या नहीं और आप जिस किसी से भी अनुसंधान के बारे में सहज महसूस करते हैं, उससे बात कर सकते हैं।

मधुमेह न्यूरोपैथी दीर्घकालिक मधुमेह के रोगियों में सबसे आम जटिलता है। न्यूरोपैथी को परिधीय छोरों से शुरू करने के लिए जाना जाता है और इस प्रकार यह टखने के जोड़ को काफी हद तक प्रभावित करता है। टखने की पैर वितरण को प्रभावित करने से टखने की गतिशीलता भी प्रभावित होती है। तंत्रिका गतिशीलता को गति की सीमा में सुधार करने और इस प्रकार पादप पाद दबाव के वितरण को सही करने के लिए उपयोग किया जाएगा। आपकी भागीदारी से पहले, एक अन्वेषक आपकी बीमारी और समस्या को निर्धारित करने के लिए आपका संक्षिप्त चिकित्सा इतिहास लेगा, जो आपको भाग लेने के लिए योग्य बना देगा। आपको खुद की उम्र के बारे में सामान्य जानकारी प्रदान करने के लिए कहा जाएगा और कुछ सामान्य पैरामीटर भी दर्ज किए जाएंगे। आपको एक विषय संख्या सौंपी जाएगी ताकि आपका नाम अध्ययन के किसी भी निष्कर्ष के साथ जुड़ा न हो।

इस शोध में आपकी भागीदारी स्वैच्छिक है। यह आपकी पसंद है कि भाग लेना है या नहीं। यदि आप इस शोध में भाग नहीं लेना चाहते हैं तो आपको ऐसे उपचार की पेशकश की जाएगी जो नियमित रूप से DPN के रोगियों के लिए दिया जाता है। आपको किसी भी समय अध्ययन से हटने का अधिकार है।

हम सभी प्रतिभागियों को एक एकल समूह में आवंटित करेंगे। सभी प्रतिभागियों को निचले छोरों के तंत्रिका गतिशीलता प्राप्त होगी।

इस अध्ययन में भागीदारी का जोखिम न्यूनतम है और हमारे हस्तक्षेप का कोई दुष्प्रभाव नहीं होगा।

प्रतिभागी की सुरक्षा सुनिश्चित करने के लिए, ज़ोर से और स्पष्ट निर्देश प्रशासित किया जाएगा। एक कर्मचारी सुरक्षा सुनिश्चित करने के लिए विषय के पास खड़ा होगा। हम आपकी यात्रा और भागीदारी के लिए आपको भुगतान करने में सक्षम नहीं हो सकते क्योंकि हमारी परियोजना वित्त पोषित नहीं है।

इस शोध परियोजना से हम जो जानकारी एकत्र करते हैं, उसे गोपनीय रखा जाएगा। आपके बारे में जानकारी जो अनुसंधान के दौरान एकत्र की जाएगी, उसे हटा दिया जाएगा और कोई नहीं, लेकिन शोधकर्ता इसे देख पाएंगे। आपके बारे में कोई भी जानकारी आपके नाम के बजाय उस पर एक नंबर होगा। केवल शोधकर्ताओं को पता होगा कि आपका नंबर क्या है और हम उस जानकारी को लॉक और कुंजी के साथ लॉक करेंगे। इसे किसी के साथ साझा या दिया नहीं जाएगा।

इस शोध को करने से हमें जो ज्ञान प्राप्त होता है, वह सामुदायिक बैठकों के माध्यम से आपके साथ साझा किया जाएगा, इससे पहले कि इसे व्यापक रूप से जनता के लिए उपलब्ध कराया जाए। गोपनीय जानकारी साझा नहीं की जाएगी। समुदाय में छोटी बैठकें होंगी और इनकी घोषणा की जाएगी। इन बैठकों के बाद, हम परिणाम प्रकाशित करेंगे ताकि अन्य इच्छुक लोग हमारे शोध से सीख सकें।

Annexure IV

Berg Balance Scale

Berg Balance Scale

1. SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

2. STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on.
( ) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

4. STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assist to sit

5. TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

6. STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely
( ) 0 needs help to keep from falling

7. STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

Berg Balance Scale continued.....

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is place in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

12. PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touch the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

13. STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on.
( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

Annexure V

Pedalo®-Sensomove Balance Device assessment sheet

Sensbalance Software - Baseline Measurement
Maharishi Markandeshawr Institute of Physiotherapy and Rehabilitation

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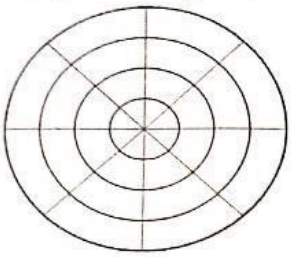
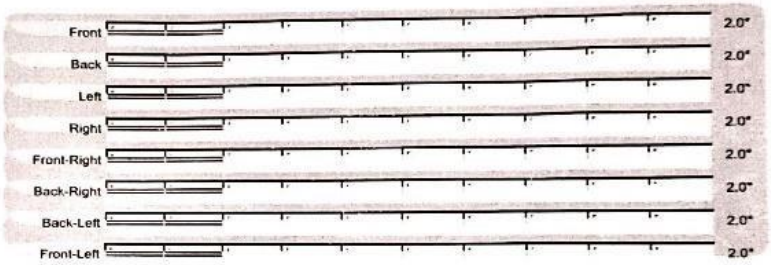
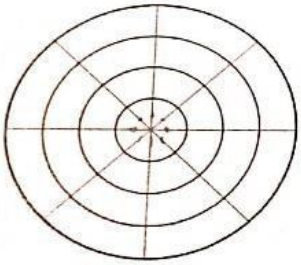
15 Deg.

Range of Motion (ROM)

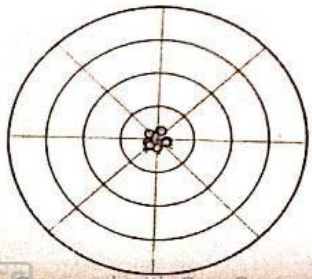




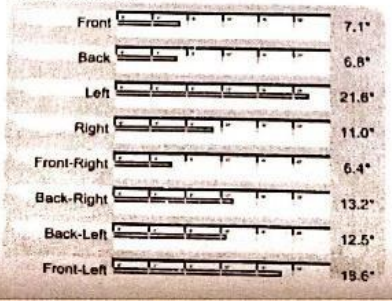
Static Balance



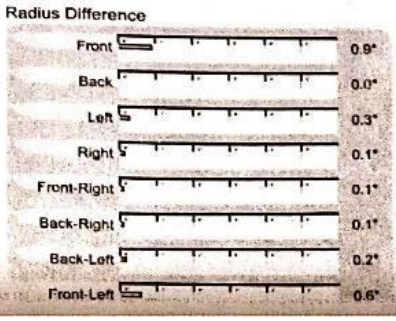
Proprioception



Angle Difference



Radius Difference



Scanned with CamScanner

Annexure VI

LANSS pain scale

THE LANSS PAIN SCALE

Leeds Assessment of Neuropathic Symptoms and Signs

NAME_____ **DATE**_____

This pain scale can help to determine whether the nerves that are carrying your pain signals are working normally or not. It is important to find this out in case different treatments are needed to control your pain.

A. PAIN QUESTIONNAIRE

- Think about how your pain has felt over the last week.
- Please say whether any of the descriptions match your pain exactly.

1) Does your pain feel like strange, unpleasant sensations in your skin? Words like pricking, tingling, pins and needles might describe these sensations.

a) NO - My pain doesn't really feel like this..... (0)

b) YES - I get these sensations quite a lot..... (5)

2) Does your pain make the skin in the painful area look different from normal? Words like mottled or looking more red or pink might describe the appearance.

a) NO - My pain doesn't affect the colour of my skin..... (0)

b) YES - I've noticed that the pain does make my skin look different from normal .... (5)

3) Does your pain make the affected skin abnormally sensitive to touch? Getting unpleasant sensations when lightly stroking the skin, or getting pain when wearing tight clothes might describe the abnormal sensitivity.

a) NO - My pain doesn't make my skin abnormally sensitive in that area..... (0)

b) YES - My skin seems abnormally sensitive to touch in that area..... (3)

4) Does your pain come on suddenly and in bursts for no apparent reason when you're still. Words like electric shocks, jumping and bursting describe these sensations.

a) NO - My pain doesn't really feel like this ..... (0)

b) YES - I get these sensations quite a lot ..... (2)

5) Does your pain feel as if the skin temperature in the painful area has changed abnormally? Words like hot and burning describe these sensations

a) NO - I don't really get these sensations..... (0)

b) YES - I get these sensations quite a lot ..... (1)

B. SENSORY TESTING

Skin sensitivity can be examined by comparing the painful area with a contralateral or adjacent non-painful area for the presence of allodynia and an altered pin-prick threshold (PPT).

1) ALLODYNIA

Examine the response to lightly stroking cotton wool across the non-painful area and then the painful area. If normal sensations are experienced in the non-painful site, but pain or unpleasant sensations (tingling, nausea) are experienced in the painful area when stroking, allodynia is present.

a) NO, normal sensation in both areas ..... (0)

b) YES, allodynia in painful area only ..... (5)

2) ALTERED PIN-PRICK THRESHOLD

Determine the pin-prick threshold by comparing the response to a 23 gauge (blue) needle mounted inside a 2 ml syringe barrel placed gently on to the skin in a non-painful and then painful areas.

If a sharp pin prick is felt in the non-painful area, but a different sensation is experienced in the painful area e.g. none / blunt only (raised PPT) or a very painful sensation (lowered PPT), an altered PPT is present.

If a pinprick is not felt in either area, mount the syringe onto the needle to increase the weight and repeat.

a) NO, equal sensation in both areas ..... (0)

b) YES, altered PPT in painful area ..... (3)

SCORING:

Add values in parentheses for sensory description and examination findings to obtain overall score.

TOTAL SCORE (maximum 24) .....

If score < 12, neuropathic mechanisms are **unlikely** to be contribution to the patient's pain

If score ≥ 12, neuropathic mechanisms are **likely** to be contributing to the patient's pain

Annexure VII

MNSI

Patient Version

MICHIGAN NEUROPATHY SCREENING INSTRUMENT

A. History (To be completed by the person with diabetes)

Please take a few minutes to answer the following questions about the feeling in your legs and feet. Check yes or no based on how you usually feel. Thank you.

1.	Are you legs and/or feet numb?	☐ Yes	☐ No
2.	Do you ever have any burning pain in your legs and/or feet?	☐ Yes	☐ No
3.	Are your feet too sensitive to touch?	☐ Yes	☐ No
4.	Do you get muscle cramps in your legs and/or feet?	☐ Yes	☐ No
5.	Do you ever have any prickling feelings in your legs or feet?	☐ Yes	☐ No
6.	Does it hurt when the bed covers touch your skin?	☐ Yes	☐ No
7.	When you get into the tub or shower, are you able to tell the hot water from the cold water?	☐ Yes	☐ No
8.	Have you ever had an open sore on your foot?	☐ Yes	☐ No
9.	Has your doctor ever told you that you have diabetic neuropathy?	☐ Yes	☐ No
10.	Do you feel weak all over most of the time?	☐ Yes	☐ No
11.	Are your symptoms worse at night?	☐ Yes	☐ No
12.	Do your legs hurt when you walk?	☐ Yes	☐ No
13.	Are you able to sense your feet when you walk?	☐ Yes	☐ No
14.	Is the skin on your feet so dry that it cracks open?	☐ Yes	☐ No
15.	Have you ever had an amputation?	☐ Yes	☐ No

Total: _____

MICHIGAN NEUROPATHY SCREENING INSTRUMENT

B. Physical Assessment (To be completed by health professional)

1. Appearance of Feet

	Right	**Left**
a. Normal	☐ 0 Yes ☐ 1 No	Normal ☐ 0 Yes ☐ 1 No
b. If no, check all that apply:		If no, check all that apply:
Deformities	☐	Deformities ☐
Dry skin, callus	☐	Dry skin, callus ☐
Infection	☐	Infection ☐
Fissure	☐	Fissure ☐
Other	☐	Other ☐
specify: _____		specify: _____

	Right		**Left**	
	Absent	Present	Absent	Present
2. Ulceration	☐ 0	☐ 1	☐ 0	☐ 1

	Present	Present/ Reinforcement	Absent	Present	Present/ Reinforcement	Absent
3. Ankle Reflexes	☐ 0	☐ 0.5	☐ 1	☐ 0	☐ 0.5	☐ 1

	Present	Decreased	Absent	Present	Decreased	Absent
4. Vibration perception at great toe	☐ 0	☐ 0.5	☐ 1	☐ 0	☐ 0.5	☐ 1

	Normal	Reduced	Absent	Normal	Reduced	Absent
5. Monofilament	☐ 0	☐ 0.5	☐ 1	☐ 0	☐ 0.5	☐ 1

Signature:_____ Total Score _____ /10 Points

ANNEXURE VIIII

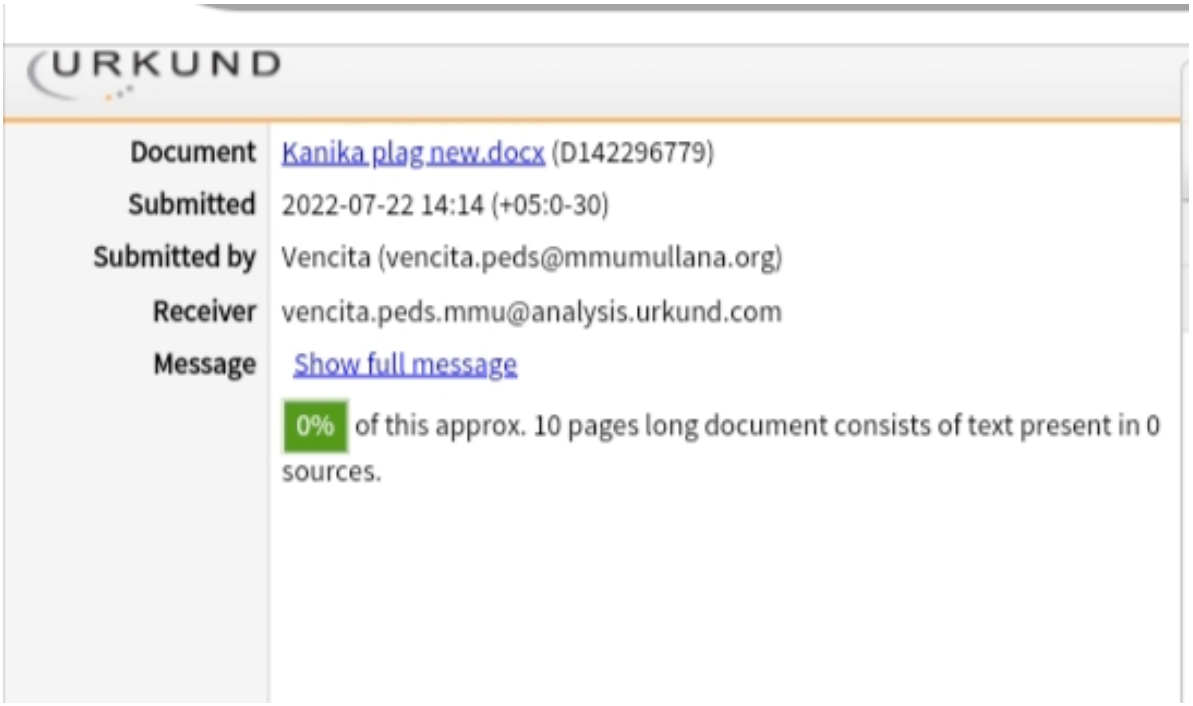
BMI CLASSIFICATION

Classification	BMI (Kg/m^2)	Risk of co-morbidities
Underweight	<18.5	Low (but increased risk of other clinical problems)
Normal Range	18.5-22.9	Average
Overweight	≥23	
At risk Obese I Obese II	23-24.9 25-25.9 ≥30	Increased Moderate Severe

Citation: World Health Organization. The Asia-Pacific perspective: redefining obesity and its treatment. 2020

Annexure IX

Plagiarism Report



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